**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k061751

**B. Purpose for Submission:**

New device

**C. Measurand:**

Urinary/Cerebrospinal Fluid Protein

**D. Type of Test:**

Calibrator materials

**E. Applicant:**

Dade Behring Inc.

**F. Proprietary and Established Names:**

Dimension Vista™ System Urinary/Celebrospinal Fluid Protein Calibrator (UCFP CAL – KC260)

**G. Regulatory Information:**

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| Calibrator, secondary (JIT) | Class II | 21 CFR 862.1150 Calibrator | 75 Clinical Chemistry (CH) |

**H. Intended Use:**

1. Intended use(s):

   The UCFP CAL is an *in vitro* diagnostic product for the calibration of the Urinary/Cerebrospinal Fluid Protein (UCFP) method on the Dimension Vista™ System.

2. Indication(s) for use:

   See Intended use above.

3. Special conditions for use statement(s):

   Prescription use only

4. Special instrument requirements:

   Dimension Vista System

## I. Device Description:

The UCFP CAL is an aqueous product containing dilute human serum. The kit consists of three vials of Calibrator A. The volume per vial is 1.5 mL. UCFP CAL is ready for use, where no preparation is required. System water is used as the UCFP zero calibrator (Level 1) for the Dimension Vista™ System.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® Urinary/Cerebrospinal Fluid Protein Calibrator

2. Predicate K number(s):

   k934843

3. Comparsion with predicate:

| | Device | Predicate |
|---|---|---|
| **Item** | **Dimension Vista™ System Urinary/Celebrospinal Fluid Protein Calibrator** | **Dimension® Urinary/Cerebrospinal Fluid Protein Calibrator** |
| **Intended Use** | **The UCFP CAL is an *in vitro* diagnostic product for the calibration of the Urinary/Cerebrospinal Fluid Protein (UCFP) method on the Dimension Vista™ System.** | **Dimension® Urinary/Cerebrospinal Fluid Protein Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Urinary/Cerebrospinal Fluid Protein (UCFP) method.** |
| **Analytes** | **Urinary/Cerebrospinal Fluid Protein** | **Urinary/Cerebrospinal Fluid Protein** |
| **Form** | **Liquid** | **Liquid** |
| **Traceability** | **NIST SRM 927(1)** | **NIST SRM 927(1)** |
| **Matrix** | **Aqueous product containing dilute human serum** | **Saline solution containing human serum albumin and IgG** |
| **Levels** | **One level (level 2). Level 1 is system water** | **Five levels** |

## K. Standard/Guidance Document Referenced (if applicable):

| STANDARDS |
|---|
| **Title and Reference Number** |
| Stability Testing of In Vitro Diagnostic Reagents (13640) |
| Medical devices - Application of risk management to medical devices (14971:2000) |

| Other Standards |
|---|

| GUIDANCE | | | |
|---|---|---|---|
| **Document Title** | **Office** | **Division** | **Web Page** |
| **Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final** | **OIVD** | | **http://www.fda.gov/cdrh/ode/calibrator.html** |
| **Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use** | | | **http://www.fda.gov/cdrh/ocd/guidance/4444.html** |

## L. Test Principle:

Not applicable

## M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Not Applicable

   b. *Linearity/assay reportable range:*

      Not Applicable

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      ***Tracebility:***
      The assigned values of the Urinary/Cerebrospinal Fluid Protein Calibrator are traceable to the National Institute of Standards and Technology- Standard Reference Material 927.

      ***Stability:***
      Target shelf life for the Dimension Vista™ System Urinary/Cerebrospinal Fluid Protein Calibrator is 12 months. Calibrator shelf life is determined by

comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change should be less than or equal to 3%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc. A vial punctured by the instrument and stored on board is stable for seven days. An open vial not stored on board of the instrument, but recapped and stored in a refrigerator is stable for 31 days. For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 8, 15, 22, and 32 versus freshly opened vials.

***Value Assignment:***
The purified human IgG and human serum albumin are added gravimetrically to stock solution at target concentrations and verified using an instrument calibrated with Master Pool assigned values. Calculated quantities of human serum stock solution are added to base matrix (aqueous solution) in appropriate concentrations for one calibrator level. The test calibrator level is verified using an instrument calibrated with the Master Pool assigned values. The final bottle assignment for test calibrator level of the commercial lot is tested N = 90 replicates, with multiple reagent lots on multiple instruments.

*d. Detection limit:*

Not applicable

*e. Analytical specificity:*

Not applicable

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.